

^c Examples include use of fume hoods, use of protective clothing/gear by laboratory personnel, chemical inactivation of wastes, separation of hazardous from nonhazardous wastes, and subsequent disposal by a firm licensed for this purpose.

6. *Compliance with Federal, State, and local environmental and occupational requirements.* Cite and include a statement of compliance with applicable emissions requirements (including occupational) at the Federal, State, and local level. Discuss the effect that the proposed research will have upon compliance with these requirements.

7. *List of preparers:* Those persons preparing the assessment together with their qualifications (expertise, experience, professional disciplines) shall be listed. Persons and agencies consulted shall also be listed.

8. *Certification:* The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the prospective contractor or applicant submitting the environmental assessment.

(Date) _____

(Signature of responsible official)

(Title) _____

(Approved by the Office of Management and Budget under control number 0910–0190)

[50 FR 16656, Apr. 26, 1985, as amended at 50 FR 30267, July 25, 1985]

§ 25.31d Environmental assessment for establishment of tolerances or action levels—Format 4.

For proposed actions to establish tolerances or action levels for unavoidable poisonous or deleterious substances in food for human or animal consumption or in packaging materials intended for use with human food and animal feed, the agency will prepare an environmental assessment in the following format:

ENVIRONMENTAL ASSESSMENT

1. *Description of the proposed action:* Describe the proposed action, the regulatory authority for the proposed action, the underlying purpose of and need for the proposed action, and how the proposed action addresses the underlying purpose and need for action.

2. *Environmental consequences of the proposed action:* Describe the potential environmental impacts of the proposed action including effects on natural resources and energy, effects on food production, effects on land use, and impacts resulting from increased use and changes in use patterns for chemical substances.

3. *Mitigation measures:* Describe measures which would be taken to avoid or mitigate potential adverse environmental effects associated with the proposed action.

4. *Description of regulatory alternatives to the proposed action and the expected environmental consequences:* Describe in detail the environmental impact of reasonable alternatives to the proposed action (including no action), particularly those that will enhance the quality of the environment and avoid some or all of the adverse environmental effects of the proposed action.

5. *Comparative analysis of proposed action and alternatives:* Provide a comparative analysis of the environmental benefits and risks of the proposed action and alternatives. Identify the preferred action based on environmental factors.

6. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall also be listed.

7. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

§ 25.31e Environmental assessment for destruction of condemned, enjoined, detained, or recalled articles—Format 5.

For actions to destroy or dispose of articles condemned after seizure, detention, or FDA-initiated recall, or after distribution or use of the article has been enjoined, the person proposing the action shall, at the request of the agency, prepare an environmental assessment in the following format when the method of destruction or disposition results in release of toxic substances:

ENVIRONMENTAL ASSESSMENT

1. *Purpose of and need for action:* Briefly describe the underlying purpose and need for the article to be destroyed, the proposed method of destruction or disposal, the locations where the proposed destruction or other disposal will occur, and the types of environments present at and adjacent to those locations.

2. *Description of potentially toxic substances present in the article:* Provide complete nomenclature, CAS Registry numbers (if available), molecular weight, structural formulae, physical description, and concentration of the potentially toxic substances in the article.

3. *Introduction of potentially toxic substances into the environment:* For transport of the article to the site(s) of disposition, cite and

certify compliance with any applicable Federal, State, and local emissions requirements. List to the extent possible the potentially toxic substances expected to enter the environment at the site(s) of destruction and/or disposal of the article. Describe the approximate concentrations of emissions; state the controls exercised; and include a citation of, and statement of compliance with, applicable requirements at the Federal, State, and local level.

4. *Fate of potentially toxic emitted substances in the environment:* Report physical/chemical and other data in the scientific literature relating to the fate of potentially toxic substances expected to be emitted into the environment as a result of destruction or other disposal of the article. Such physical/chemical parameters include water solubility, solubility in organic solvents, *n*-octanol/water partition coefficient, dissociation constants, vapor pressure, ultraviolet-visible absorption spectrum, ability to form chemical complexes, storage stability, etc.

5. *Environmental effects of potentially toxic substances expected to be emitted into the environment:* Report information on the effects of the emitted substances on animals, plants, humans, other organisms, and effects at the ecosystem level. Compare the expected environmental concentrations of the substances with the concentrations that cause adverse effects.

6. *Description of alternative methods of destruction and/or disposal and the expected environmental consequences:* Describe the environmental impact of reasonable alternatives (including no action) particularly those that will enhance the quality of the environment and that will avoid some or all of the adverse environmental effects of the proposed method of destruction or other disposition.

7. *Comparative analysis of proposed methods of destruction or other disposition and alternative methods:* Provide a comparative analysis of the environmental benefits and risks of the proposed and alternative methods. Identify the preferred action based on environmental factors.

8. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall also be listed.

9. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

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[50 FR 16656, Apr. 26, 1985, as amended at 50 FR 30267, July 25, 1985]

§25.32 Finding of no significant impact.

(a) As defined by the CEQ regulations (40 CFR 1508.13), a finding of no significant impact (FONSI) is a document prepared by a Federal agency and stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

(b) If the EA has been prepared by an applicant or petitioner, the agency may choose to include additional evidence in the FONSI. Any remaining unknowns or uncertainties will be identified.

(c) The agency official(s) responsible for the preparation and approval of the FONSI will sign the document, thereby establishing that the official(s) approve(s) the conclusions not to prepare an EIS for the action under consideration.

§25.33 Notice of intent.

(a) As defined by CEQ regulations (40 CFR 1508.22), the Notice of Intent notifies the public that the agency has determined that an EIS will be prepared. This determination may be based on information contained in an EA or on other information available to the agency which indicates that potentially significant effects may be associated with a proposed action.

(b) As required by 40 CFR 1508.22, the Notice of Intent will describe the proposed action, possible alternatives, the agency's proposed scoping process, which may include a request for information or suggestions regarding the scope of the EIS and notice of public meetings, and the identification of persons within the agency to contact for further information.

§25.34 Draft, final, and supplemental environmental impact statements.

(a) The CEQ regulations (40 CFR part 1502) provide detailed requirements for the preparation of an EIS. CEQ's format for EIS's (40 CFR 1502.10) will be followed unless the agency determines that there is a compelling reason to do otherwise.